

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS : Suggy S. Chrai et al.  
SERIAL NO. : Not Assigned  
FILED : Herewith  
FOR : Pharmaceutical Product  
and Method of Making  
EXAMINER : Not Assigned  
ART UNIT: : Not assigned  
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PRELIMINARY AMENDMENT

Box Patent Application  
Commissioner for Patents  
Washington, DC 20231

Sir:

This amendment accompanies a continuation application and is preliminary.

Please calculate the filing fee after entry of this amendment.

IN THE SPECIFICATION

Amend the specification as follows:

Page 1, line 24, after "Pletcher et al." insert --08/659,501 now US Pat. No.  
6,007,630--.

Page 2, line 2, after "chucks," insert --now US Pat. No. 5,846,595--;

line 7, after "Sun et al," insert --now US Pat. No. 5,858,099--.

lines 13 and 14, replace "(Attorney Docket SAR 12914)" with --09/095,246  
now US Pat. No. 6,063,194--;

line 15, replace "(Attorney Docket SAR 12610)" with --09/095,425 now US Pat. No. 6,149,774--;

line 16, after "Chucks" " insert --filed June 10, 1998--;

line 17, replace "(Attorney Docket SAR 12384)" with --09/095,321; and

line 18, after "Substrate," " insert --filed June 10, 1998--.

Page 15, line 20, replace "(Attorney Docket SAR 12384)" with --09/095,321.

Page 16, line 11, replace "(Attorney Docket SAR 12384)" with --09/095,321.

Page 24, lines 6 and 7, replace "(Attorney Docket SAR 12610)" with --09/095,425 now US Pat. No. 6,149,774--.

Page 31, line 5, replace "(SAR 12384)" with --09/095,321--.

Page 32, lines 3 and 4, replace "(Attorney Docket SAR 12914)" with --09/095,246 now US Pat. No. 6,063,194--

Page 38, line 2, replace "(Attorney Docket SAR 12914)" with --09/095,246 now US Pat. No. 6,063,194--.

Page 49, line 5, change "by" to --be--.

#### IN THE CLAIMS

Amend the claims as follows:

1 (Amended). A product comprising:

a package; and

a plurality of discrete pharmaceutical or diagnostic unit dosage forms associated with the package, each unit dosage form including at least one active ingredient, said at least one active ingredient being present in each of the unit forms in an amount which does not vary from a predetermined target amount by more than about 5 weight per cent.

2 (unchanged). The product of claim 1 wherein the package comprises a container and the unit forms are physically separate and independent from one another.

3 (Amended). The product of claim 1 wherein the unit forms are selected from the group consisting of any one of a diagnostic reagent, tablet, caplet, a unit amount of an active drug powder and a capsule.

4 (Unchanged). The product of claim 1 wherein each of the unit forms are solid.

5 (Amended). The product of claim 1 wherein the unit forms are attached to laminated strips of substrate films and sealed thereto by a surrounding bond.

6 (Amended). A method of forming a drug dosage or diagnostic product comprising forming a plurality of discrete pharmaceutical or diagnostic unit dosage forms, each unit form including at least one active ingredient, said at least one active ingredient being present in each of the unit forms in an amount which does not vary from a predetermined target amount by more than about 5 weight per cent.

7 (Amended). The method of claim 6 including optically scanning the unit forms in a raster scan to produce scan signals and calculating the amount of active ingredient in each unit form from the scan signals.

8 (Unchanged). The method of claim 7 wherein the scanning employs optical profilometry to produce said signals.

9 (Unchanged). The method of claim 7 wherein the scanning employs diffuse reflection to produce said signals.

10. The product of claim 1 wherein the dosage forms each comprise a base substrate comprising a first polymer on which the active ingredient is deposited and a cover substrate comprising a second polymer joined to the first substrate by a bond that surrounds the active ingredient.

11. (Canceled)

12. (Canceled)

13. (Canceled)

14. Canceled)

15. (Canceled)

16. (canceled)

17 (Amended). A product comprising:

a package; and

a plurality of diagnostic or pharmaceutically active unit dosage forms associated with the package, each unit form including at least one diagnostic or pharmaceutically active ingredient, said at least one active ingredient being present in each of the unit dosage forms in an amount which does not vary from a given target amount by more than a predetermined value.

18 (Amended). The product of claim 17 wherein the predetermined value is about 5 weight per cent.

19 (Amended). A diagnostic reagent kit comprising a plurality of separate unit forms of a diagnostic reagent each unit form comprising a diagnostic reagent deposited on a base substrate wherein the amount of diagnostic reagent in each unit form does not vary from a predetermined target amount by more than 5 weight per cent.

20 (Canceled).

Add the following claims:

21. A product comprising a pharmaceutical or diagnostic unit form, the unit form comprising:

a first base substrate film comprising a first polymer;

a first deposit, including an active ingredient disposed on a first surface of said first base substrate film; and

a cover substrate film comprising a second polymer, the cover substrate film covering the first deposit and joined to said first base substrate film by a first bond that surrounds said deposit, said active ingredient being present in an amount that does not vary from a target amount by more than 5 weight per cent.

22. The product of claim 21, further having a plurality of unit forms, said plurality of unit forms comprising plural deposits disposed on said first surface of the first base substrate film, wherein the plural deposits are covered by said cover substrate film and each surrounded by said bond.

23. The product of claim 21, wherein said first base substrate film comprises a planar film.

24. The product of claim 23, wherein said cover substrate film comprises a planar film.

25. The product of claim 24, wherein said cover substrate film has a shape comprising a plurality of semi-spherical bubbles, wherein said plural deposits are disposed within a perimeter of said semi-spherical bubbles, one deposit to one semi-spherical bubble.

26. The product of claim 25, wherein said first base substrate film has a shape comprising a plurality of semi-spherical bubbles, wherein the plural deposits are disposed within a perimeter of said semi-spherical bubbles, one deposit to one semi-spherical bubble.

27. The product according to claim 21, wherein said deposit has a shape that is substantially circular, and said deposit has a size in the range of about 3 millimeters to about 8 millimeters.

28. The product according to claim 21, wherein said first polymer comprises a thermoplastic material.

29. The product according to claim 21, wherein said first polymer is selected from the group consisting of polyvinylacetate, hydroxypropylmethylcellulose, polyethylene oxide, polypropylene, polyester and polyamide films.

30. The product according to claim 21, wherein said first polymer and said second polymer are the same.

31. The product according to claim 21, wherein said first base substrate film and said cover substrate film are ingestible.

32. The product of claim 22, wherein said first base substrate film is separated into at least a first portion and a second portion, wherein some of said plural deposits are disposed on said first portion, and others of said plural deposits are disposed on said second portion.

33. The product of claim 21, further comprising:

a second base substrate film; and

a second deposit, including a second active ingredient, that is disposed on a first deposition surface of said second base substrate film, wherein

said second deposit and said first deposition surface overlie said first base substrate film such that a portion of said first base substrate film that is surrounded by said first bond is encapsulated by said second base substrate film.

34. The product of claim 33, wherein said first base substrate film is interposed between said first deposit and said second deposit.

35. The product of claim 33, wherein a portion of said second base substrate film is disposed on said cover substrate film and joined thereto by a second bond that surrounds said first bond.

36. A product comprising:

a base substrate having a plurality of deposits each comprising a pharmaceutically active ingredient, the deposits being disposed on discrete regions of a first surface of the base substrate and being formed by generating an electrostatic force at said discrete regions, and directing a cloud of charged grains towards said first surface of the base substrate; and

a cover substrate that overlies the plurality of depositions and is joined to the first surface of the base substrate by bonds that individually surround each of said depositions, the active ingredient in each deposition being present in an amount that does not vary from a target amount by more than about 5 weight percent.

37. The product of claim 36, wherein the cover substrate has a planar form that includes a plurality of concavities, each concavity overlying a deposit, and further wherein the bonds individually surround each concavity.

#### REMARKS

Claims 1-10, 17-19 and 21-37 are active. Claims 11-16 and 20 are canceled. Claims 21-37 are new. This amendment is preliminary and accompanies a continuation application.

Amendment is made to certain of the claims and to the specification to add the relevant serial and patent numbers of the various applications noted in the specification and to correct a typographical error. Enclosed is a copy of the amended claims marked up in red ink to show the changes. The claims are believed allowable.

Mlodozeniec is foreign to the claims as this reference does not disclose or suggest the claim 1 structure:

said at least one active ingredient being present in each of the unit forms in an amount which does not vary from a predetermined target amount by more than about 5 weight per cent.



This reference does not disclose enabling apparatus to produce such structure.

The remaining claims all include similar structure or corresponding step and are believed allowable for similar reasons.

Entry of this amendment is respectfully requested.

Respectfully submitted,  
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